

Department of Health and Human Services

Office of Inspector General Projects



PUBLIC HEALTH AGENCIES Table of Contents

AGENCY FOR HEALTHCARE RESEARCH AND QUALITY

Patient Safety Efforts	1
------------------------------	---

CENTERS FOR DISEASE CONTROL AND PREVENTION

Ethics and Conflict of Interest - Review Panels	1
Oversight of Grants	1
Funding for AIDS Activities	2
State and Local Bioterrorism Preparedness and Response	2
Prevention Research Center Program	2
Breast and Cervical Cancer Medicaid Benefit for Uninsured Women	3
Released INS Detainees With Tuberculosis	3
Controls Over Physical Security	3

FOOD AND DRUG ADMINISTRATION

Oversight of Imported Food	4
Prescription Drug User Fee Act	4
Sponsors' Oversight of Clinical Trials	4
Biennial Inspection Requirement	5
Postmarketing Studies of Prescription Drugs	5
Effectiveness of MedWatch	5
Pharmaceutical Company Gifts and Payments to Providers	6
Medical Device Reviews	6
Accreditation and Quality Oversight of Mammography Facilities	6
Bioterrorism Research Program	6
Laboratory Security	7

HEALTH RESOURCES AND SERVICES ADMINISTRATION

Reducing Perinatally Transmitted HIV	7
HIV/AIDS Care and Prevention: Collaboration Among HHS Grantees	7
AIDS Education and Training Centers	8
Eligibility for Ryan White CARE Act Funding.....	8
Conformity of State AIDS Drug Assistance Programs With Public Health Treatment Guidelines	8
Ryan White CARE Act Title III Evaluation Systems.....	9
Administration and Oversight of Ryan White CARE Act Funds	9
State Administration of AIDS Funds	9
Hemophilia Treatment Centers' Access to Blood Clotting Factor at 340B Prices	10
Section 340B Drug Ceiling Prices	10
Hemophilia Treatment Centers' Disposition of 340B Program Income and Patient Choice Policy	10
Multiple Registrations for Organ Transplantation	11
Organ Donation at Transplant Hospitals.....	11
Healthcare Integrity and Protection Data Bank	11
Controls Over Travel and Outside Activities.....	12

INDIAN HEALTH SERVICE

Alcohol and Substance Abuse Programs	12
Prescription Drug Contracts With Tribes.....	12

NATIONAL INSTITUTES OF HEALTH

Superfund Financial Activities for Fiscal Year 2001.....	13
Cancer Information Service Outreach Program.....	13
Oversight of Grants	13
Funding of General Clinical Research Centers.....	14
Recruiting Human Subjects for Clinical Trials.....	14
Commercialization of NIH-Funded Inventions	14
Security of NIH Laboratories.....	15

SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION

Dissemination of Mental Health Technology Information	15
Community Support Program	15

PUBLIC HEALTH AGENCIES-WIDE ACTIVITIES

Government Information Security Reform Act	16
Disclosure Statements Filed by Colleges and Universities.....	16
Cash Management at Colleges and Universities.....	16
Research Management Service Costs	17
Recipient Capability Audits	17
Reimbursable Audits.....	17
Indirect Cost Audits	17
Followup on Nonfederal Audits.....	18

INVESTIGATIONS

Referrals by Office of Research Integrity	18
---	----

AGENCY FOR HEALTHCARE RESEARCH AND QUALITY

Patient Safety Efforts

We will evaluate the progress of the Agency for Healthcare Research and Quality in improving patient safety and reducing medical errors. In a 1999 report on medical errors and patient safety, "To Err Is Human, Building a Safer Health Care System," the Institute of Medicine noted that, based on studies in New York, Utah, and Colorado, 44,000 to 98,000 persons die each year in hospitals as a result of medical errors. The report recommended the establishment of a Center for Patient Safety in the Agency for Healthcare Research and Quality and outlined a detailed agenda for the proposed center.

OEI; 00-00-00000

CENTERS FOR DISEASE CONTROL AND PREVENTION

Ethics and Conflict of Interest - Review Panels

We will assess the Centers for Disease Control and Prevention (CDC) controls to preclude conflicts of interest on the part of employees involved in the research awards process. These employees, who are members of review panels, are responsible for evaluating the scientific or technical merit of proposals being considered for funding. The CDC funds extramural research through, for example, the Prevention Research Center Program, which supports a prevention research agenda at schools of public health throughout the country. In evaluating potential research and awarding funds, CDC employees are obliged to maintain objectivity and integrity.

OAS; W-00-02-50003; A-04-02-00000

Oversight of Grants

We will review CDC's oversight of its external grants. In FY 2000, through its extramural program, CDC awarded approximately \$2.1 billion to State, local, and territorial health departments; colleges and universities; nonprofit organizations; and other entities. These awards supported CDC's initiatives in such critical areas as childhood immunization, disease prevention, and AIDS education. Our review will determine whether CDC has adequate

controls to ensure that grantees properly carry out their programmatic and fiscal management responsibilities.

OAS; W-00-02-50003; A-04-02-00000

Funding for AIDS Activities

At the request of the Deputy Secretary, we will review concerns regarding CDC's fiscal and administrative practices for AIDS-related funds. In FY 2001, the agency was appropriated over \$1 billion in funding to prevent and control HIV/AIDS.

OAS; W-00-02-50003; A-04-02-00000

State and Local Bioterrorism Preparedness and Response

We will examine the activities of State and local health departments to support preparedness and response to a terrorist attack involving a biological or chemical agent. Since 1999, CDC's Bioterrorism Preparedness and Response Program has awarded over \$40 million in annual funding, through cooperative agreements with State and local health departments, to improve the national capacity to address biological and chemical terrorism. A national assessment of the effectiveness of this program has never been conducted. This review will identify CDC, State, and local responsibilities; partnerships; and bioterrorism preparedness plans and prevention efforts. We will also look at how State and local health departments spent the Federal funding they received and whether this spending enhanced bioterrorism preparedness and response.

OEI; 00-00-00000

Prevention Research Center Program

This review will evaluate the impact of the National Center for Chronic Disease Prevention and Health Promotion's Prevention Research Center Program on community public health programs and policies. Since 1986, this program has funded academic institutions across the country to develop, in collaboration with the communities they serve, health promotion and disease prevention strategies and apply them at the community level. The program has never been evaluated. This study will attempt to identify common indicators of successful community-based health promotion and disease prevention programs and best practices.

OEI; 00-00-00000

Breast and Cervical Cancer Medicaid Benefit for Uninsured Women

We will assess the collaboration of CDC, the Centers for Medicare and Medicaid Services, and the States in implementing the Medicaid treatment benefit for low-income, uninsured women with breast or cervical cancer. Under the Breast and Cervical Cancer Prevention and Treatment Act of 2000, States receive enhanced matching funds to provide full Medicaid benefits to uninsured women under age 65, with incomes up to 250 percent of poverty, who are identified as needing treatment for breast or cervical cancer through CDC's National Breast and Cervical Cancer Early Detection Program. This program has been in operation since 1991. Successful implementation of the new Medicaid benefit requires a coordinated effort between State Medicaid and public health agencies and between the Centers for Medicare and Medicaid Services and CDC. This review will focus on the nature and extent of the collaboration and the impact of the new benefit on the existing CDC-funded breast and cervical cancer early detection programs.

OEI; 00-00-00000

Released INS Detainees With Tuberculosis

We will assess the extent and effectiveness of the Public Health Commission Corps' efforts to control tuberculosis in paroled illegal immigrants with tuberculosis. The Immigration and Naturalization Service (INS) is responsible for the detention of illegal immigrants before their deportation. About 400 to 500 illegal immigrants in detention facilities who are awaiting dispositional hearings are paroled each month into the community. Commission Corps staff, who provide health care in INS detention facilities, give paroled individuals with tuberculosis a "starter" supply of medicine, and the individuals are expected to follow up with local medical authorities. However, neither INS nor Commission Corps personnel formally follow up on these individuals to ensure that they continue treatment once paroled. Lapses in treatment can lead to continued tuberculosis transmission and development of drug-resistant tuberculosis.

OEI; 00-00-00000

Controls Over Physical Security

We will follow up on actions taken by CDC to improve controls over physical security at headquarters facilities in Atlanta, Georgia. In response to an OIG audit report, CDC agreed in July 1996 to specific actions to improve controls at these facilities. In FY 1997 appropriations, the Congress provided CDC with \$23 million to begin security improvements.

We will determine whether our previous recommendations have been implemented and whether additional safeguards are necessary.

OAS; W-00-01-50003; A-04-01-04003

FOOD AND DRUG ADMINISTRATION

Oversight of Imported Food

We will assess the effectiveness of Food and Drug Administration (FDA) strategies for overseeing imported foods and ensuring their safety. Since 1992, the level of food imports has increased three-fold and is expected to continue to increase. Currently, about 38 percent of produce and about 50 percent of the seafood consumed in the United States is imported. The FDA relies on seven key strategies to oversee imports: border exams, foreign inspections, equivalency determinations, country assessments, technical assistance to foreign governments, sample surveys of imported foods, and responses to emergencies. We will quantify the recent growth of food imports into the United States, consider the strategies being used to oversee food imports and their effectiveness in ensuring the safety of imported food, and assess how effectively FDA is allocating its limited resources among the various strategies.

OEI; 00-00-00000

Prescription Drug User Fee Act

At the request of the FDA Center for Drug Evaluation and Research, we will review the effects of the Prescription Drug User Fee Act on the regulatory review of new drug applications. We will examine the FDA process for reviewing these applications under the act and identify process and program areas that can improve the effectiveness and stringency of these reviews.

OEI; 01-01-00590

Sponsors' Oversight of Clinical Trials

We will examine how sponsors of clinical trials monitor the implementation of the trials by clinical investigators. Sponsors are drug, device, or biologic manufacturers that plan to submit an application for FDA approval. They are responsible for ensuring that their clinical trials are conducted in accordance with FDA's regulations by selecting qualified clinical investigators, providing the clinical investigators with the information needed to conduct the clinical investigation, and reviewing ongoing clinical investigations. Sponsors, along with

institutional review boards and clinical investigators, provide the first line of defense in protecting human subjects from harm.

OEI; 00-00-00000

Biennial Inspection Requirement

In a series of three reviews, we will assess FDA's strategy for meeting its statutory mandate to inspect registered human drug, animal drug, biologic, and device manufacturing establishments at least once every 2 years. According to FDA, the agency has not been able to meet this requirement because of limited resources. Our reviews will focus on the effectiveness of FDA's inspection planning and execution process and the accuracy of the computerized database of more than 100,000 establishments under the agency's jurisdiction that must be inspected. Only a fraction of these establishments are subject to the biennial inspection requirement.

OAS; W-00-01-50004; A-15-01-20001

Postmarketing Studies of Prescription Drugs

We will follow up on FDA's practices regarding the monitoring of postmarketing studies of prescription drugs. A 1996 OIG report provided recommendations for improving FDA's system for monitoring and tracking studies requested after drugs were approved for marketing. We will review FDA's progress in implementing our recommendations and its tracking of postmarketing studies.

OEI; 00-00-00000

Effectiveness of MedWatch

We will evaluate the effectiveness of MedWatch, the FDA Medical Products Reporting Program, and its web-based postings on product safety and labeling changes for industry and health care professionals. MedWatch provides and solicits reports of adverse events and product problems; educates providers, manufacturers, and patients; and serves as the "front door" for the drug and device adverse event reporting system database. The MedWatch program is intended to enhance the effectiveness of postmarketing surveillance of medical products as they are used in clinical practice and to rapidly identify significant health hazards associated with these products. However, it is estimated that only 1 to 10 percent of adverse events are actually reported.

OEI; 00-00-00000

Pharmaceutical Company Gifts and Payments to Providers

We will evaluate the extent of gifts and payments to physicians from pharmaceutical companies. In 1990, FDA passed regulations forbidding “gifts of substantial value” to physicians from pharmaceutical companies. Nevertheless, the pharmaceutical industry currently spends about \$12 billion a year on marketing to physicians, and some of these gifts may present an inherent conflict of interest between the legitimate business goals of manufacturers and the ethical obligation of providers to prescribe drugs in the most rational way. Gifts may also violate the Federal anti-kickback statute if they are intended to induce referrals.

OEI; 00-00-00000

Medical Device Reviews

We will evaluate the effectiveness of FDA’s premarket review processes for both new and investigational medical devices, as well as those devices that have been “grandfathered” pending approval. One of the objectives of the 1997 Food and Drug Administration Modernization Act was to shorten the time needed to approve medical devices by using contractors as auxiliary review staff. Concerns have been raised about the potential for reviewer bias and about the recall of certain medical devices soon after they come to market.

OEI; 00-00-00000

Accreditation and Quality Oversight of Mammography Facilities

We will assess the accreditation and regulatory oversight mechanisms for mammography facilities since the enactment of the Mammography Quality Standards Act of 1992. In response to the growing concern over breast cancer and the quality of mammography services, the act established national quality standards for mammography. Responsibility for this legislation was delegated to the FDA Center for Devices and Radiological Health Mammography Program. This study, a followup to a 1994 OIG report, will evaluate the impact on the quality of mammography screenings and services.

OEI; 00-00-00000

Bioterrorism Research Program

We will assess FDA’s actions to implement its bioterrorism research program. The FDA included \$11.5 million in its FY 2001 budget request to develop vaccines, diagnostic products, and rapid detection methods to counter bioterrorism threats. This review will build on an earlier assessment, conducted at the request of the Subcommittee on Oversight and

Investigations, House Committee on Commerce, of FDA's FY 2000 activity in bioterrorism research.

OAS; W-00-01-50004; A-15-01-30002

Laboratory Security

We will review the physical security and security controls at FDA to determine whether the agency has established and maintained a security program adequate to protect its research laboratories and ensure the safety of FDA employees and the American people. Our review will include FDA laboratory facilities in the Washington, D.C., metropolitan area, as well as other locations.

OAS; W-00-02-50004; A-03-02-00000

HEALTH RESOURCES AND SERVICES ADMINISTRATION

Reducing Perinatally Transmitted HIV

This study will evaluate technical assistance that the Health Resources and Services Administration (HRSA) and the Department offer to assist States in reducing the incidence of perinatal HIV transmission. Approximately 6,000 to 7,000 HIV-infected women give birth every year. Because many HIV-positive pregnant women are unaware of their HIV status and therefore do not receive treatment, the number of children born with HIV is still unacceptably high. We will estimate the total number of HIV-positive infants born in the United States during FY 1999 for whom the mother's HIV status was unknown to the attending obstetrician. We will also identify barriers that may discourage or prevent an obstetrician from routinely testing all pregnant woman and/or all newborns whose mothers' HIV status is unknown.

OEI; 05-01-00260

HIV/AIDS Care and Prevention: Collaboration Among HHS Grantees

This study will evaluate the nature and extent of collaboration among community-based organizations funded by departmental grant programs to improve prevention and care for people with HIV/AIDS. In recent years, increasing Federal grant money has been distributed directly to community-based organizations serving individuals with HIV/AIDS. However,

some of these organizations may be duplicating efforts or crafting programs that are not responsive to the needs of their communities.

OEI; 00-00-00000

AIDS Education and Training Centers

We will determine whether regional AIDS education and training centers and local performance sites have adapted to significant changes in the HIV/AIDS epidemic and identify best practices for adapting to such changes. Under the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act, HRSA awards grants to 14 regional education and training centers and over 70 local performance sites to provide state-of-the-art treatment education, training, consultation, and support to health care professionals treating HIV-positive patients. Since the mid-1990s, two trends in the epidemic have become particularly relevant to this program: the increasing impact of HIV/AIDS on the underserved, minority, and marginalized segments of society and the dramatic impact of new clinical treatment modalities on health outcomes of people living with HIV/AIDS.

OEI; 00-00-00000

Eligibility for Ryan White CARE Act Funding

This followup review will determine whether a Northeastern city and its contracted service providers ensure that clients are qualified to receive services under Title I of the Ryan White CARE Act. The act authorizes emergency funding relief to metropolitan areas with the highest incidences of HIV disease. In FY 2000, the city received \$12.5 million in CARE Act funds to be used for a range of community-based services, such as outpatient health care, home health care, housing and transportation assistance, and inpatient case management services. In a previous review, OIG identified problems with the city's ability to properly document the eligibility of CARE Act clients.

OAS; W-00-02-50005; A-01-02-00000

Conformity of State AIDS Drug Assistance Programs With Public Health Treatment Guidelines

We will evaluate whether eligibility criteria and the availability of therapeutics within State AIDS Drug Assistance Programs conform to public health agencies' guidelines for the treatment of HIV/AIDS. The HRSA requires States to use a portion of Title II Ryan White CARE Act funding to establish Drug Assistance Programs for low-income people diagnosed with HIV. States have wide latitude in establishing program eligibility criteria and formularies

that may not be consistent with the most recent guidelines for the treatment of HIV disease and related infections.

OEI; 00-00-00000

Ryan White CARE Act Title III Evaluation Systems

We will assess the evaluation systems used by Ryan White Title III grantees to monitor service inputs and outputs and to track the outcomes of the people they serve and the program impact within targeted communities. Title III grants go directly to community-based organizations to expand their ability to provide early intervention and primary care services for people with HIV/AIDS. Grantees are responsible for designing and executing their own evaluation systems. While some grantees have implemented fully functional evaluation systems, others have not. This study will follow up on our earlier reviews of Titles I and II and the AIDS Drug Assistance Program of the Ryan White CARE Act.

OEI; 00-00-00000

Administration and Oversight of Ryan White CARE Act Funds

At the request of the Senate Committee on Finance, we will review administration of funds awarded to grantees--eligible metropolitan areas and States--and subgrantees under the Ryan White CARE Act. In FY 2001, CARE Act appropriations totaled over \$1.8 billion. We will examine the grantees' expenditures, fiscal capabilities, and program performance as well as HRSA's monitoring of grantees' administrative actions.

OAS; W-00-02-50005; Various CINs

OEI; 00-00-00000

State Administration of AIDS Funds

We will review the administration of Ryan White CARE Act funds by a State and its contractor. The HRSA asked us to focus our review on the contractor's fiscal and administrative practices and its stewardship of CARE Act funds, the State's administrative and fiscal processes related to contractor oversight, and the propriety of the State's practice of providing all Care Act funds to the contractor to carry out grantee obligations.

OAS; W-00-01-50005; A-05-01-00073

Hemophilia Treatment Centers' Access to Blood Clotting Factor at 340B Prices

At HRSA's request, we will examine hemophilia treatment centers' ability to purchase blood clotting factor in general and at 340B discounted prices. Section 340B of the Public Health Service Act authorizes grantees to purchase covered drugs at discounted prices by entering into contracts with the prime vendor. Since this law was passed, HRSA has received anecdotal information that blood clotting factor has not been available to some hemophilia treatment centers at the 340B price.

OAS; W-00-01-50005; A-15-01-30001

Section 340B Drug Ceiling Prices

We will review the rebate percentage calculations used by drug manufacturers to determine the ceiling prices for outpatient drugs sold to covered 340B entities. Manufacturers' "best price" determinations for Medicaid-covered drugs are used as a basis for computing the 340B prices. As pointed out in a March 2001 OIG report, some drug manufacturers improperly excluded from their Medicaid best price determinations sales to repackagers that were also health maintenance organizations. As a result, the Medicaid program lost drug rebates totaling \$80.7 million. This review will determine whether covered 340B entities were also overcharged and, if so, quantify the impact.

OAS; W-00-01-50005; A-06-01-00060

Hemophilia Treatment Centers' Disposition of 340B Program Income and Patient Choice Policy

At HRSA's request, we will assess hemophilia treatment centers' disposition of income obtained from participating in the 340B discount pricing program for the purchase of blood clotting factor and evaluate their policies on patient choice of providers of blood clotting factor. According to grant requirements, hemophilia treatment centers are to use program income to complement or expand the services provided by the program. The HRSA officials have expressed concern that some centers that purchase blood clotting factor at the 340B price have used the profits for activities unrelated to patient care. There is also concern that some centers have limited patients' rights to choose their blood clotting factor provider.

OAS; W-00-01-50005; A-03-01-03500

Multiple Registrations for Organ Transplantation

We will examine the United Network for Organ Sharing (UNOS) policy that allows patient registrations at more than one transplant center and the impact of the policy on Medicare costs.

According to UNOS data, approximately 5 percent of patients (about 8,200 individuals) on waiting lists were registered at more than one transplant center for the period 1995 through 1999. For Medicare-eligible patients, Medicare covers all costs relating to multiple registrations, including the \$400 UNOS fee that is required for registering at each center and the costs of initial and ongoing medical evaluations and lab work. Debate about the distribution of scarce organs to transplantation has included the issue of whether patients should have the right to place themselves on waiting lists at several transplant centers, thereby gaining an advantage over other potential donors.

OEI; 00-00-00000

Organ Donation at Transplant Hospitals

We will assess the performance of hospital organ transplant programs in organ donation.

About 260 medical institutions operate hospital organ transplant programs in the United States.

To help alleviate the organ shortage, Medicare conditions of participation required that hospitals, as of August 21, 1998, notify organ procurement organizations about individuals whose deaths are imminent or who die in the hospital. Because of their recognition of the need for organ donation, it seems logical that hospitals that operate transplant programs would be leaders in organ donation. Despite this expectation, there are indications that donation rates at hospitals with transplant programs are considerably lower than those at other hospitals.

OEI; 00-00-00000

Healthcare Integrity and Protection Data Bank

We will review the implementation of the Healthcare Integrity and Protection Data Bank

(HIPDB). The Health Insurance Portability and Accountability Act of 1996 directed the Secretary of the Department of Health and Human Services, acting through OIG and the U.S. Attorney General, to create HIPDB to help combat fraud and abuse in health care delivery.

The HIPDB is a national data bank containing “adverse actions” taken against health care practitioners and suppliers; such adverse actions include OIG exclusions, criminal convictions, and civil judgments related to health care. The HRSA operates HIPDB under a memorandum of agreement with OIG.

OEI; 00-00-00000

Controls Over Travel and Outside Activities

We will review HRSA's internal controls regarding travel; outside employment activities; and use of staff fellows, expert consultants, and specially paid employees. Departmental management has raised concerns about the appropriateness of past practices in these areas and the need for controls to ensure compliance with applicable laws, regulations, and policies.

OAS; W-00-01-50005; A-03-01-00351

INDIAN HEALTH SERVICE

Alcohol and Substance Abuse Programs

We will follow up on Indian Health Service (IHS) progress in achieving the goals of the Indian Alcohol and Substance Abuse Prevention and Treatment Act of 1986. This act was designed to provide a coordinated and comprehensive plan to address the problem of Indian alcohol and substance abuse, particularly among young people. In several studies conducted in the early 1990s, we identified a number of problems in implementing the act, including a failure to meet quality assurance objectives, ineffective information management systems, inappropriate use of funds, and a failure to establish regional treatment centers and emergency shelters. This study will focus on IHS policies and procedures that promote coordination of Indian alcohol and substance abuse programs.

OEI; 00-00-00000

Prescription Drug Contracts With Tribes

We will review IHS drug distribution systems for tribes that purchase prescription drugs under Federal discount pricing programs. The IHS is authorized to access various Federal discount drug programs. Based on information and inquiries from some contractors and from the IHS Regional Supply Service Center, there is reason to believe that questionable activity may be occurring in the IHS contractors' purchase or distribution of pharmaceuticals, such as unusually large-volume orders or resale to entities not entitled to the discounts. This study will identify the extent to which these concerns need to be addressed.

OEI; 00-00-00000

NATIONAL INSTITUTES OF HEALTH

Superfund Financial Activities for Fiscal Year 2001

As required by Superfund legislation, we will conduct this annual financial audit of the National Institute of Environmental Health Sciences payments, obligations, reimbursements, and other uses of Superfund monies. The Institute's Superfund activities, carried out by its own staff and through cooperative agreements, include training people engaged in hazardous waste activities and studying the effects of exposure to specific chemicals. During FY 2000, agency obligations and disbursements of Superfund resources amounted to \$62.9 million and \$59.4 million, respectively.

OAS; W-00-02-50025; A-04-02-00000

Cancer Information Service Outreach Program

This study will evaluate the National Cancer Institute's Cancer Information Service outreach program. The mission of the program is to disseminate cancer information to "the medically underserved, including minority groups and people with limited access to health information and services." Similar to the Cancer Information Service's toll-free phone service, the outreach program disseminates information via 19 regional contractors. Unlike the phone service, outreach program staff do not interact directly with the public; instead, they partner with State and regional organizations that serve the target audiences. This study will examine issues relating to the outreach program's target audiences and the effectiveness of specific outreach program activities.

OEI; 00-00-00000

Oversight of Grants

We will review the National Institutes of Health (NIH) oversight of its external grants. In FY 2001, NIH spent about \$15.7 billion to support biomedical research, primarily at colleges and universities. With continuing congressional support, this amount is expected to increase significantly in the coming years. We will assess NIH's effectiveness in ensuring that grantees properly carry out their research and fiscal management responsibilities.

OAS; W-00-02-50025; A-15-02-00000

Funding of General Clinical Research Centers

We will assess the effectiveness of NIH procedures for awarding funds to general clinical research centers. For FY 2001, NIH estimated that it would award \$227 million to more than 75 centers nationwide. The mission of these centers is to provide a research infrastructure for clinical investigators who receive their primary support from NIH components and other Federal agencies. The NIH uses two approaches to fund the centers. Under the discrete method, the expected cost of research days, nursing, and other fixed expenses is calculated in the grant award, and the grant must be reimbursed when the center uses the facilities for nonresearch patients. Under the per diem basis, the center is reimbursed for the research days actually used. Previous OIG reviews revealed problems with the discrete funding method. This review will determine whether NIH has an adequate process for determining the most effective form of center funding.

OAS; W-00-01-50025; Various CINs

Recruiting Human Subjects for Clinical Trials

This followup will assess investigator efforts to recruit human subjects for NIH clinical trials in a timely fashion. Difficulties in recruiting an adequate number of human subjects for clinical trials have been blamed for a quarter of the delays in developing new drugs. We will determine the extent and nature of these difficulties, and we will describe the range of recruitment strategies and oversight of recruitment practices.

OEI; 00-00-00000

Commercialization of NIH-Funded Inventions

This evaluation will determine how NIH has applied the mandate of the Bayh-Dole Act of 1980 to commercialize publicly funded inventions on reasonable terms. Government-funded biomedical research, dominated by the NIH extramural grant program, is integral to improving public health by advancing medical technology to prevent, diagnose, and treat diseases. The “practical application” clause of the Bayh-Dole Act applies broadly to most inventions funded in part or entirely by the Federal Government and licensed to the private sector on either an exclusive or a nonexclusive basis. The law mandates that these inventions be not merely made available to the public, but available at “reasonable terms.” This study will examine the practical application of the law and its impact on commercial research.

OEI; 00-00-00000

Security of NIH Laboratories

At the request of the Subcommittee on Oversight and Investigations, House Committee on Commerce, we will determine whether physical security of research laboratories at NIH is adequate to contain hazardous materials. The Subcommittee specifically requested that we examine NIH security controls for bioterrorism research and controls for ensuring that physical security funds are appropriately spent. We will also assess physical security at FDA laboratories on the NIH Bethesda, Maryland, campus.

OAS; W-00-01-50025; A-04-01-04001

SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION

Dissemination of Mental Health Technology Information

This study will assess the Substance Abuse and Mental Health Services Administration (SAMHSA) role in disseminating research knowledge and best practices for treating mental illness to the treatment community. The SAMHSA supports a national network of technical assistance centers to disseminate information on promising, evidence-based prevention and treatment interventions, as well as best practices resulting from mental health research. In addition, the agency offers community action and other grants to induce communities to test new practices and adopt them if they work.

OEI; 00-00-00000

Community Support Program

This review will assess SAMHSA's response to our June 1993 report on the Community Support Program. The program, which is funded at about \$20 million annually, provides grants to State mental health authorities for services, research demonstrations, and projects involving consumers and families in the development of services. Our 1993 study made a number of recommendations for improvements.

OEI; 05-01-00440

PUBLIC HEALTH AGENCIES-WIDE ACTIVITIES

Government Information Security Reform Act

As required by the Government Information Security Reform Act of 2000, we will evaluate the eight public health agencies' security programs and their critical systems. The results of this effort will be included in the Department's annual report to the Office of Management and Budget (OMB) and the Congress, as required by law.

The purpose of the Government Information Security Reform Act is to provide a comprehensive framework for establishing and maintaining effective controls over the information resources that support Federal operations and assets. It also creates a mechanism for improved oversight of Federal agency information security programs to ensure compliance with applicable laws and regulations regarding computer security. The law has two requirements for the OIG: to conduct reviews of each operating division's security program and to test an appropriate subset of the Department's critical systems.

OAS; W-00-02-40016; Various CINs

Disclosure Statements Filed by Colleges and Universities

Our continuing reviews will assist the Department's Division of Cost Allocation in determining the adequacy and compliance of college and university disclosure statements. The OMB Circular A-21, revised May 8, 1996, requires that colleges and universities disclose their cost accounting practices in disclosure statements. The statements are designed to promote uniformity and consistency in the cost accounting practices followed by colleges and universities and to ensure that only allowable costs are claimed and that costs are equitably allocated to Federal projects. We will determine whether the cost accounting practices presented in the disclosure statements are complete, accurate, current, and consistent with cost accounting standards and OMB Circulars A-21 and A-110.

OAS; W-00-02-50007; Various CINs

Cash Management at Colleges and Universities

We will evaluate the cash management procedures used by selected colleges and universities to account for Federal funds awarded by the Department and other agencies. In FY 2000, colleges and universities were awarded about \$10 billion from the Department alone. The OMB Circular A-110 requires that the institutions limit the amount and timing of cash withdrawals to immediate needs and remit any interest earned to the Federal Treasury. We will also evaluate the institutions' processes for determining funding requests and reconciling

the Federal Cash Transactions Report with their accounting records. As a result of four similar prior audits, institutions remitted \$1.4 million in interest income.

OAS; W-00-01-50025; Various CINs

Research Management Service Costs

We will review the allowability of research management service costs charged by a university to federally funded awards from July 1, 1994, through June 30, 2001. The OMB Circular A-21 states that costs incurred for the same purpose in like circumstances should be treated consistently as either direct costs or facilities and administrative costs.

OAS; W-00-01-50012; A-09-01-04003

Recipient Capability Audits

At the public health agencies' requests, we will perform recipient capability audits of new organizations having little or no experience managing Federal funds. These audits will determine the adequacy of the organizations' accounting and administrative systems and their financial capabilities to satisfactorily manage and account for Federal funds. Such reviews provide management with strengthened oversight of new grantees.

OAS; W-00-02-50013; Various CINs

Reimbursable Audits

We will conduct a series of audits in accordance with the Department's responsibility to negotiate the indirect cost rates for approximately 95 percent of the Nation's nearly 3,000 colleges and universities. Audit cognizance requires that we perform audits at these schools, including those requested by other Federal agencies. Our audits may include activities related to the review of disclosure statements filed by universities in conjunction with the cost accounting standards incorporated in OMB Circular A-21.

OAS; W-00-02-50012; Various CINs

Indirect Cost Audits

We will provide assistance, as requested, to the Department's Division of Cost Allocation on specific indirect cost issues at selected institutions. In previous years, we reviewed such issues as library allocations, medical liability insurance, internal service funds, fringe benefit rates,

and space allocations. These audits helped to substantially reduce indirect cost rates at the institutions reviewed.

OAS; W-00-02-50010; Various CINs

Followup on Nonfederal Audits

These reviews will determine whether auditees have implemented the recommendations in prior nonfederal audit reports to correct reported findings. The OIG's National External Audit Review Center has identified certain prior audits by nonfederal auditors as having circumstances that need further investigation.

OAS; W-00-02-50019; Various CINs

INVESTIGATIONS

Referrals by Office of Research Integrity

As a result of a closer relationship forged between the OIG's Office of Investigations (OI) and the Office of Research Integrity (located in the Office of the Assistant Secretary for Health), OI expects to investigate more scientific misconduct cases referred by that Office. These matters may involve allegations of fiscal improprieties, such as embezzlement or misappropriation of funds, or other fraudulent activity, such as falsification or fabrication of research data or plagiarism of confidential materials or intellectual property. Under departmental policies, the Office of Research Integrity may not directly investigate such issues but refers them to OIG when appropriate.